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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,495	03/09/2004	Jon S. Wilson	3600/290	3046

7590 01/27/2009
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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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01/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/796,495	Applicant(s) WILSON ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/6/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment filed on 10/14/08 has been entered.

Claims 32-54 are present for examination.

Claims 1-31 are cancelled.

Applicant's arguments filed on 10/14/08 have been fully considered but are not persuasive.

Therefore, claims 32-54 are rejected in the same ground rejections as set forth in the office action mailed 4/16/08.

Terminal Disclaimer

The terminal disclaimer filed on 10/14/08 disclaiming the terminal portion of any patent granted on this application has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

Claims 32 and 41 are objected to because of the following informalities: a recitation "the multi-lumen catheter comprising a multi-lumen tube portion, a proximal end...a single lumen distal arterial tube portion each having a distal end" is not positive recitation. Therefore, the Examiner interprets this imitation as functional recitation. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 32-54 are rejected under 35 U.S.C. 102(e) as being e by anticipated Schon (US 6,682,519).

As noted that, Applicant defines the term "proximal" referred to those portions of a catheter inserted into an area of a patient's body such as a blood vessel; and the term "distal" for connection to a fluid exchange device, such as a dialysis machine or the like (Specification on page 11, lines 7-15). Meanwhile, Schon discloses opposite way. For example: the proximal portion 34, 36 referred as portions of a catheter inserted into the blood vessel, and the distal portions 59, 61 of catheters referred as portions of catheter that outwardly from the patient's body.

Schon discloses a method of surgically implanting a multi-lumen catheter into a patient, the multi-lumen catheter comprising: a multi-lumen tube portion, a proximal end 38, 40 comprising a single-lumen portion venous portion 34 and single lumen arterial portion 36. As noted that, the elements 34, 36 can be swapped names such as venous portion 36 and the arterial portion 34. A distal end 59 includes a single lumen distal venous tube portion; and a single lumen distal arterial tube 61 having a distal end.

The method comprising: making an incision in the skin of the patient at portion 70, inserting the catheter sheath 69 through the incision (Figs. 1-3 or col. 4, lines 45+). The shape and size of sheath may vary to accommodate the shape of a catheter to catheters (can be catheters 16, 18) placed together (col. 10, lines 4-7); forming a subcutaneous tunnel 50, 54 having a first end proximate to the incision 70 and a second end 60, 64 distance from the first end of the tunnel (col. 2, lines 42+); guiding the distal end 59, 61 of the catheter and at least a portion of the multi-lumen tube portion through the subcutaneous tunnel (col. 2, line 50+; col. 10, line 63-col. 11, line 29) such as at least the distal ends 59, 61 of the distal venous and distal arterial tube portions extend outwardly from the second end 60, 64 of the tunnel (Figs. 4-5); a stabilizing cuff 14.

Response to Arguments

Applicant's arguments filed 10/14/08 have been fully considered but they are not persuasive.

1. Applicant argues that: the two or more lumens 5, 6 are formed within a single one –piece catheter tube. In contrast, Schon discloses a multi-lumen catheter assembly 10 made from two separate catheters 16 and 18.

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First, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., two or more lumens 5 and 6 are formed within a single one-piece catheter tube) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Second, a recitation "the multi-lumen catheter comprising a multi-lumen tube portion, a proximal end...a single lumen distal arterial tube portion each having a distal end" is not positive recitation. Therefore, the Examiner interprets this imitation as functional recitation.

Third, Schon clearly discloses that the structure is similarly with the device of Schon. Please see the rejection above for more details.

2. Applicant argues that Schon does not teach or suggest guiding "at least a portion of the multi-lumen tube portion through the subcutaneous tunnel".

In response, Schon clearly discloses that the subcutaneous tunnels are preferably formed using a tunneling device (not show) such as a stainless steel trocar which, for example, attaches to the first proximal end 59 (equivalent as a distal end of claimed invention) of the first proximal portion 48 (same as the first distal portion of claimed invention) of the first catheter 16 and pulls the proximal portion 48 beneath the skin while forming a subcutaneous tunnel 56. The end 59 of the proximal portion 48 is drawn by the device percutaneously out through an opening 60, and so on... (col. 11, lines 2-33). Also, please see the rejection above for more details.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763